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10/572,639	03/17/2006	Yoshitaka Tomigahara	2006_0369A	5260
513 7590 06/20/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
EXAMINER SOLOLA, TAOFTQ A				
ART UNIT		PAPER NUMBER		
1625				
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06/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/572,639

**Applicant(s)**

TOMIGAHARA ET AL.

**Examiner**

Taofiq A. Solola

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-49, 51, 53, 54, 56, 58, 61, 63, 65, 67, 69, 71 and 73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-49, 51, 53-54, 56, 58, 61, 63, 65, 67, 69, 71, 73 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

Claims 1-49, 51, 53-54, 56, 58, 61, 63, 65, 67, 69, 71, 73, are pending in this application.

Claims 50, 52, 55, 57, 60, 62, 64, 66, 68, 70, 72, are canceled.

## **DETAILED ACTION**

### ***Election/Restriction***

Claims 1-49, 51, 53-54, 56, 58, 61, 63, 65, 67, 69, 71, 73, are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

- I. Claims 1, 14-25, drawn to compounds of formula I, classifiable in several non-heterocyclic classes and numerous subclasses.
- II. Claim 2 drawn to compounds of formula II, classifiable in several non-heterocyclic classes and numerous subclasses.
- III. Claim 3 drawn to compounds of formula III, classifiable in several non-heterocyclic classes and numerous subclasses.
- IV. Claim 4 drawn to compounds of formula IV, classifiable in several non-heterocyclic classes and numerous subclasses.
- V. Claim 5 drawn to compounds of formula V, classifiable in several non-heterocyclic classes and numerous subclasses.

VI. Claim 6 drawn to compounds of formula VI, classifiable in several non-heterocyclic classes and numerous subclasses.

VII. Claim 7, drawn to compounds of formula VII, classifiable in several non-heterocyclic classes and numerous subclasses.

VIII. Claim 8, drawn to compounds of formula VIII, classifiable in several non-heterocyclic classes and numerous subclasses.

IX. Claim 9, drawn to compounds of formula IX, classifiable in several non-heterocyclic classes and numerous subclasses.

X. Claim 10, drawn to compounds of formula X, classifiable in several non-heterocyclic classes and numerous subclasses.

XI. Claim 11, drawn to compounds of formula XI, classifiable in several non-heterocyclic classes and numerous subclasses.

XII. Claim 12, drawn to compounds of formula XII, classifiable in several non-heterocyclic classes and numerous subclasses.

XIII. Claim 13, drawn to compounds of formula XIII, classifiable in several non-heterocyclic classes and numerous subclasses.

XIV. Claims 26-45 in part drawn to compounds of formula XXVI-1, classifiable in several non-heterocyclic classes and numerous subclasses.

XV. Claims 26-45 in part drawn to compounds of formula XXVI-2, classifiable in several non-heterocyclic classes and numerous subclasses.

XVI. Claims 26-45 in part drawn to compounds of formula XXVI-3, classifiable in several non-heterocyclic classes and numerous subclasses.

XVII. Claims 26-45 in part drawn to compounds of formula XXVI-4, classifiable in several non-heterocyclic classes and numerous subclasses.

XVIII. Claim 46, drawn to a process of making compounds of formula XLVI-1, classifiable in several non-heterocyclic classes and numerous subclasses.

XIX. Claim 47, drawn to a process of making compounds of formula XLVII, classifiable in several non-heterocyclic classes and numerous subclasses.

XX. Claim 48, drawn to a process of making compounds of formula XLVIII, classifiable in several non-heterocyclic classes and numerous subclasses.

XXI. Claim 49, drawn to a process of making compounds of formula XLIX, classifiable in several non-heterocyclic classes and numerous subclasses.

XXII. Claims 51,53-54, 56, 58-59, 61, 73 drawn to methods of using compound of formula I, classifiable in several non-heterocyclic classes and numerous subclasses.

XXIII. Claim 63 drawn to method of using compound of formula II, classifiable in several non-heterocyclic classes and numerous subclasses.

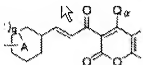
XXIV. Claim 65 drawn to method of using compound of formula III, classifiable in several non-heterocyclic classes and numerous subclasses.

XXV. Claim 67 drawn to method of using compound of formula IV, classifiable in several non-heterocyclic classes and numerous subclasses.

XXVI. Claim 69 drawn to method of using compound of formula X, classifiable in several non-heterocyclic classes and numerous subclasses.

XXVII. Claim 71 drawn to method of using compound of formula XI, classifiable in several non-heterocyclic classes and numerous subclasses.

1. In the instant inventions, the only structural element shared by groups I-XXVII is



. However, the structure is not novel. See WO 03/080592. Therefore, under PCT Rules 13.1 and 13.2, the structure does not constitute a corresponding special technical feature among the groups.

2. Each of the different methods of use of the inventions set forth in Group XXII is unrelated to the others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use of the compounds are unrelated because the patient populations being treated are different.

If applicant elects any of the method of use invention or in a rejoinder thereof applicant must elect a specific disease and the method would be examined commensurate in scope therewith.

3. In an election of any of Groups I-XXVII, an election of a single compound (or set of compounds) is further required including an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl, and each subsequent variable position.

In the instant case, Applicant must elect one representative for each of A, X, Y, Q, L, M, p and q in the applicable formula, and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic so as to define a species, and the species must be disclosed in the specification. Part of the species corresponding to each substituent in applicable formula must be identified.

Upon election of a single compound (or set of compounds), the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with process of using said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compounds and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R.

1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject

matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

June 15, 2008



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